Prospective multi-center study elucidating patient experience after prostatic urethral lift

Neal Shore, MD,[1] Sheldon Freedman, MD,[2] Steven Gange, MD,[3] William Moseley, MD,[4] Sean Heron, MD,[5] Ron Tutrone, MD,[6] Thomas Brown, MD,[7] Jack Barkin, MD[8]

[1]Carolina Urologic Research Center, Myrtle Beach, South Carolina, USA
[2]Sheldon J. Freedman, M.D., Ltd, Las Vegas, Nevada, USA
[3]Jean Brown Research, Salt Lake City, Utah, USA
[4]Premier Urology/San Diego Uro-Research, San Diego, California, USA
[5]Pinellas Urology, Inc, St. Petersburg, Florida, USA
[6]Chesapeake Urology Research Associates, Daytona Beach, Florida, USA
[7]Atlantic Urological Associates, Towson, Maryland, USA
[8]Department of Surgery, University of Toronto, Toronto, Ontario, Canada

SHORE N, FREEDMAN S, GANGE S, MOSELEY W, HERON S, TUTRONE R, BROWN T, BARKIN J. Prospective multi-center study elucidating patient experience after prostatic urethral lift. *Can J Urol* 2014; 21(1):7094-7101.

Introduction: *The prostatic urethral Lift (PUL) procedure offers a novel treatment for men with lower urinary tract obstructive symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). Most patients who seek LUTS/BPH treatment choose the intervention that offers the expectations of a significant improvement in quality of life and the least chance of short or long term morbidity. We report the results of a prospective, non-randomized study designed to further characterize the perioperative subject experience with the PUL procedure.*

Materials and methods: *The PUL procedure employs permanent implants to mechanically pull the prostatic lateral lobes apart. Subjects were ≥ 50 years old with International Prostate Symptom Score (IPSS) ≥ 12, peak flow rate ≤ 12 mL, and prostate volume between 30 cc and 80 cc. Subject experience through 1 month was characterized by validated instruments designed to assess quality of recovery, work productivity, activity impairment, symptom response, quality of life, flow rate and sexual function.*

Results: *Fifty-one subjects were treated without any serious adverse events. No case was abandoned or postponed due to subject discomfort. By 1 month, 86% of subjects achieved high quality recovery as measured by a score of ≥ 80 on the Quality of Recovery Visual Analog Scale. Ninety percent of subjects reported improvement in their condition and 75% of subjects would recommend the procedure to a friend. Symptom response, flow rate improvement, and sexual function preservation were comparable to published studies.*

Conclusions: *The PUL procedure was tolerated under local anesthesia, rarely required postoperative catheterization, and offered rapid LUTS relief with minimal associated morbidity. The study further allows urologists to advise patients regarding post-procedural expectations and side effects, inclusive of symptomatic benefit.*

Key Words: prostate, prostatic hyperplasia, benign prostatic hyperplasia, urethra, surgical procedures, minimally invasive, implant, therapeutics, sexual function

Introduction

Lower urinary tract symptoms (LUTS), in men over 50 years of age most commonly attributable to benign prostatic hyperplasia (BPH), may compromise a man's quality of life.[1] Treatment options for patients presenting with bothersome LUTS range from medical therapy to interventional procedures.[2] The modest improvements in International Prostate Symptom Score (IPSS) offered by medication may be offset by the side effects and compliance burden of a lifelong prescription. LUTS population reviews suggest that over 30% of men will discontinue medical therapy.[3] Interventional endoscopic options, including

Accepted for publication January 2014

Address correspondence to Dr. Jack Barkin, Department of Surgery, University of Toronto, 404-960 Lawrence Avenue West, Toronto, ON M6A 3B5 Canada

transurethral resection of the prostate (TURP) and laser-based alternatives, offer substantial symptom improvement but may be associated with morbidity rates as high as 20%.[4] In a recent study, researchers found that 10%-14% of patients would require an invasive procedure in the first 6 months post TURP or laser due to a related adverse event.[5] Erectile and ejaculatory dysfunction associated with TURP are 10% and 65%, respectively.[2] The potential morbidity of the traditional endoscopic interventions may be seen as a significant deterrent to the aforementioned options, particularly in younger men.

The prostatic urethral lift (PUL) procedure offers a new outpatient treatment option for the LUTS patient, which may avoid the side effects of traditional endoscopic interventions. Prior published studies have shown symptomatic improvement, objective flow rate improvements and minimal perioperative morbidity with the PUL procedure.[6-9] Furthermore, the PUL preserves both ejaculatory and erectile function.[10,11]

As PUL has recently received Food and Drug Administration (FDA) approval,[12] this study was designed to further characterize the perioperative and early postoperative recovery period. To this end, outcome measures were used to assess pelvic pain, quality of recovery, work impairment, activity impairment, and patient general impression during the first postoperative month. We present the results of a prospective, non-randomized study of the PUL procedure in 51 subjects across seven centers with the purpose of elucidating previously unreported key patient response characteristics of this novel treatment.

Materials and methods

Clinical protocol

The study design was a prospective, multicenter, non-blinded, single arm clinical trial of the UroLift System. The primary objective was to characterize the perioperative subject experience following PUL procedure when conducted under local anesthesia. Eligible subjects were at least 50 years old, provided informed consent, had no prior surgical BPH treatment, and were either washed out or naïve to alpha blockers and 5 alpha reductase inhibitors. Each subject had an International Prostate Symptom Score (IPSS) of 13 or greater, a peak flow rate (Qmax) no greater than 12 mL, and a prostate of volume as measured by transrectal ultrasound between 30 cc and 80 cc without an obstructing median lobe. Subjects were excluded for current urinary retention, post-void residual volume greater than 250 mL, active infection or gross hematuria, cystolithiasis within 3 months, and bacterial prostatitis within 1 year. The study protocol was approved by the US FDA as well as the institutional review boards at each of the seven enrolling sites.

Study procedure

The PUL mechanically addresses obstruction without thermal energy by the placement of transprostatic implants that pull the lateral lobes apart, Figure 1.[6-9,13] Permanent UroLift transprostatic implants (NeoTract, Pleasanton, CA, USA) are delivered under cystoscopic visualization typically using only local anesthesia.[8,13] The system is inserted through a 20 Fr sheath and the targeted prostatic lobe is compressed with the tip of

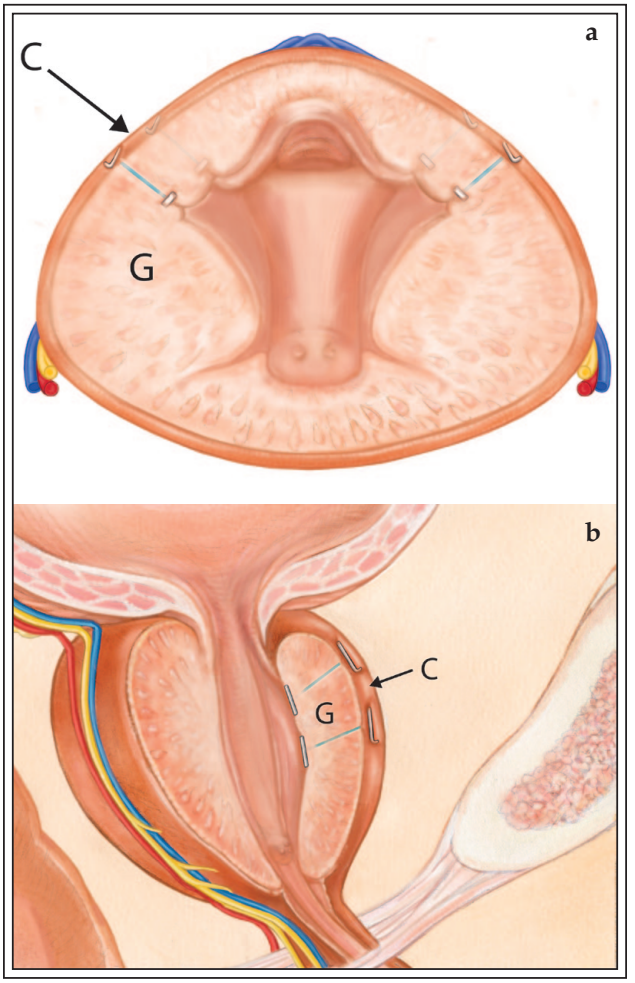

Figure 1. Tranverse **(a)** and sagittal **(b)** sectional views of prostate after prostatic urethral lift procedure. Transprostatic implants hold firmly on fibromuscular capsule **(C)**, while glandular tissue **(G)** compresses to open the prostatic fossa, reducing obstruction to urine flow. Courtesy of NeoTract, Inc.

the instrument. A hollow 19-gauge needle is advanced through the lateral prostate lobe, and a metallic tab is then seated on the prostate capsular surface. A urethral end piece is then affixed to the tensioned monofilament traversing the prostatic lobe, delivering each implant that is sized in situ to the thickness of the compressed lobe. Because the fibromuscular capsule is less compliant than the glandular tissue, the prostatic urethral surface is moved outward toward the capsule, thus opening the prostatic fossa.

Study endpoints

The study's primary effectiveness endpoint was to ascertain whether 80% of subjects achieved a score of 80 or more on the Quality of Recovery Visual Analog Scale (QoR VAS)[14] by the 1 month follow up visit. Researchers who developed the QoR VAS discriminated between "good" versus "poor" recovery with a pooled VAS score threshold of 80.[14] Patient experience before and after the procedure was captured at specific time points through a 100 mm pelvic pain visual analog scale. Pain experience during the procedure was captured through a numerical rating scale for patient ease. Postoperative experience was further measured at 2 weeks and 1 month via validated instruments such as the Patient General Impression Index (PGI-I)[15] and the Work Productivity and Activity Impairment Questionnaire (WPAI).[16] Lower urinary tract symptoms were evaluated at baseline, 2 weeks, and 1 month after PUL with the standard IPSS, IPSS Quality of Life (QoL) question,[17] and BPH Impact Index (BPHII).[18] Peak urinary flow rate and post-void residual volume were assessed at baseline and 1 month. International Index of Erectile Function (IIEF)[19,20] and the Male Sexual Health Questionnaire for Ejaculatory Function (MSHQ-EjD)[21] were assessed at baseline and 1 month after PUL in men who were sexually active. Safety was assessed at each follow up visit through adverse event reporting. An independent reviewer over-read each flow waveform using the two-second rule.[22]

Statistical methods

The primary endpoint was tested by calculating the one-sided 95% confidence limit using the Clopper-Pearson method. Descriptive statistics were used to describe the baseline and follow up values of all study parameters (IPSS, QoL, BPHII, Qmax, PVR, SHIM, and MSHQ-EjD). Additionally, a general estimating equation model (GEE) was fit to each study output parameter. Change from baseline was the dependent variable; baseline score and visit were the independent variables. In this model, an exchangeable correlation structure and identity link were used and p values for each follow up interval compared to baseline were calculated using SAS (SAS Institute, Inc. Cary, NC, USA); p values < 0.05 were considered statistically significant.

Results

Procedure

Between May 2013 and September 2013, 51 men underwent the PUL procedure as part of a non-blinded study. Average age of treated subjects was 66 ± 7.6 (range 51-85). Sixty percent (30/51) of subjects were employed and 80% (41/50) were sexually active, Table 1. At baseline, average prostate volume was 41.3 cc ± 11.6 cc, with an average Qmax of 8.2 mL ± 2.2 mL and an IPSS of 21.5 ± 5.4.

Average PUL procedure time was 52 min ± 22 min for delivering an average of 3.7 implants (range 2-6). All but one subject (50/51, 98%) underwent PUL with true local anesthesia: topical anesthetic (lidocaine) and oral sedation (alprazolam, diazepam, lorazepam, midazolam) and/or analgesia (acetaminophen oxycodone, hydrocodone, morphine). One subject (1/51, 2%) received intramuscular meperidine administration prior to the introduction of rigid

TABLE 1. **Baseline characteristics for enrolled subjects**

Characteristic	**LOCAL prostatic urethral lift (n = 51)**	
	Mean ± SD	**[min - max]**
Age (yrs)	66 ± 7.6	[51-85]
Prostate volume (cc)	41.3 ± 11.6	[30.0-77.3]
IPSS	21.45 ± 5.43	[13-32]
QoL	4.57 ± 1.02	[2-6]
BPHII	6.65 ± 3.08	[0-13]
Qmax (mL/sec)	8.22 ± 2.18	[2-12.0]
PVR (mL)	77.05 ± 74.92	[0-247]
PSA (ng/mL)	1.81 ± 1.53	[0.1-7.3]
SHIM*	16.51 ± 7.33	[2-25]
MSHQ-EjD function*	9.95 ± 2.59	[5-15]

*in sexually active men (n = 41)
IPSS = International Prostate Symptom Score; QoL = quality of life; BPHII = benign prostatic hyperplasia Impact Index; PVR = post-void residual; PSA = prostate-specific antigen; SHIM = Sexual Health Inventory for Men; MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Function

TABLE 2. **Procedure details and perioperative assessments**

Characteristic	Mean (SD) [range]
Procedure time (min)	52 (22) [8 to 131]
Implants per patient	3.7 (1.1) [2 to 6]
VAS flexible cystoscopy	3.0 (2.2) [0 to 9]
VAS rigid cystoscopy	4.8 (2.9) [0 to 10]
VAS UroLift implantation	5.0 (3.0) [0 to 10]
Return to preoperative activity* (days)	5.1 (5.8) [0 to 30]
Return to work (days)	2.8 (3.7) [0 to 17]
At 1 month	
WPAI: % work missed	0% (0%) [0%]
WPAI: % overall work impairment	3% (9%) [0 to 40%]
WPAI: % impairment in activity	8% (19%) [0 to 100%]

*two subjects (4%) had not reported return to preoperative activity by the 1 month visit
VAS = Visual Analog scale; WPAI = Work Productivity and Activity Impairment

cystoscopy as a prophylaxis for pain. No postoperative catheterization was required for 41 (80%) subjects, and the catheter duration averaged 16 hours. All subjects were treated as day patients and no one required an overnight hospital stay.

In terms of subject recovery, 28/51 (55%) at 2 weeks and 44/51 subjects (86.3%) at 1 month achieved 80 or more on the QoR VAS. The one-sided 95% lower confidence limit at 1 month was 76%. PUL subjects on average reported return to preoperative activity by 5.1 days ± 5.8 days (median 3 days) and 96% (49/51) had returned to preoperative activity by the 1 month visit, Table 2. The average number of days to return to work after PUL was 2.8 days ± 3.7 days. Per the validated WPAI which assessed the period of time from day 7 to day 14 at the 2 week time point, the average number of hours lost from work was 5.8 hours with 73% (22/30) of subjects not missing any work. Per the same instrument assessed at 1 month, the percent of work missed was 0%, percent of overall work impairment was 3% ± 9%, and the percent of impairment in activity was 8% ± 19%. Through the PGI-I assessed at 1 month, 90% reported improvement in their condition and 75% of subjects would recommend the procedure to a friend.

Pelvic pain during the procedure was tolerated with local anesthesia, as no case was postponed or abandoned due to subject discomfort. During screening, average baseline pelvic pain was found to be 0.4 out of 10 on the pelvic pain VAS. During the procedure, average pelvic pain score with flexible cystoscopy was 3.0/10, rose to 5.0/10 with UroLift implantation, and settled to 3.4/10 at the end of the procedure. Of those subjects with low pelvic pain (pain score < 3/10) during flexible cystoscopy, most subjects (17/24, 71%) reported maximum pain scores of 5 or less during PUL procedure. After PUL procedure,

TABLE 3. **Outcome following prostatic urethral lift in terms of IPSS, QoL, BPH II, peak flow rate, SHIM, and MSHQ-EjD assessments. P values were obtained from a general estimating equation**

Characteristic	Follow up	n	Baseline	Follow up	Change	% Change	(95% CI)	p value
IPSS	2 week	51	21.45 ± 5.43	15.75 ± 8.96	-5.71 ± 9.57	-23.7%	(-36.2%, -11.3%)	< 0.0001
	1 month	51	21.45 ± 5.43	10.98 ± 6.55	-10.47 ± 7.35	-47.5%	(-56.4%, -38.5%)	< 0.0001
QoL	2 week	51	4.57 ± 1.02	2.92 ± 2.05	-1.65 ± 2.28	-32.5%	(-45.9%, -19.1%)	< 0.0001
	1 month	51	4.57 ± 1.02	2.45 ± 1.71	-2.12 ± 1.94	-43.8%	(-54.5%, -33.1%)	0.0001
BPH II	2 week	51	6.65 ± 3.08	5.65 ± 3.92	-1.00 ± 4.08	-2.7%	(-26.1%, -20.79%)	0.09
	1 month	51	6.65 ± 3.08	3.24 ± 3.02	-3.41 ± 3.57	-44.5%	(-61.8%, -27.1%)	< 0.0001
Qmax	1 month	50	8.20 ± 2.19	11.50 ± 4.65	3.30 ± 4.50	47.0%	(29.4%, 64.5%)	< 0.0001
SHIM	1 month	34	17.88 ± 6.35	18.24 ± 7.33	0.35 ± 4.76	2.3%	(-7.43%, 11.95%)	0.67
MSHQ-EjD function	1 month	34	10.29 ± 2.56	11.88 ± 3.14	1.59 ± 2.75	18.6%	(6.2%, 31.1%)	0.002
MSHQ-EjD bother	1 month	34	1.82 ± 1.42	1.06 ± 1.30	-0.76 ± 1.39	-56.3%	(-73.63%, -39.0%)	0.003

IPSS = International Prostate Symptom Score; QoL = quality of life; BPHII = benign prostatic hyperplasia Impact Index; SHIM = Sexual Health Inventory for Men; MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Function

average pain score returned to the pre-procedure level of 0.4/10 by 2 weeks and improved to 0.1/10 by 1 month. For those patients with high pelvic pain score (≥ 6/10) during flexible cystoscopy prior to UroLift introduction, average maximum pain score during the procedure was 7.8/10 (n = 8).

Effectiveness

The IPSS reduction seen in this study is similar to that of prior published randomized results, improving from 21.5 ± 5.4 at baseline to 11.0 mL ± 6.6 mL at 1 month ($p < 0.001$). Improvements in quality of life, as measured through IPSS QoL and BPHII, were also similar and mirrored the IPSS symptom response, Table 3. Peak urinary flow rate increased 3.3 mL from 8.2 mL ± 2.2 mL at baseline to 11.5 mL ± 4.7 mL at 1 month ($p < 0.001$).

Sexual function was maintained after PUL. At 1 month, there was no significant change in erectile function as characterized by average SHIM (17.9 ± 6.4 at baseline to 18.2 ± 7.3 at 1 month; $p = 0.7$). Ejaculatory function as evaluated by the MSHQ-EjD score significantly improved (10.3 ± 2.6 at baseline to 11.9 ± 3.1 at 1 month; $p = 0.002$). Further, the bother associated with ejaculatory difficulties improved (MSHQ-EjD bother score reduced from 1.8 ± 1.4 at baseline to 1.1 ± 1.3 at 1 month; $p = 0.003$).

Safety

There were no serious adverse events in any subject in this study, Table 4. In addition, no subject required further surgical intervention for any LUTS related condition. The adverse events reported for PUL were typically mild to moderate and resolved within the first month. All adverse events were examined using the modified Clavien-Dindo classification and were classified as grade I.[23]

Mild to moderate hematuria was experienced by 80% of subjects and lasted for median 4 days. Dysuria occurred in 74% of subjects and lasted for median 10 days. Two subjects experienced new onset non-stress urinary incontinence, each with Incontinence Society Indices (ISI) of 4. There were no reported events of erectile dysfunction or retrograde ejaculation/anejaculation.

Discussion

This prospective, multi-center study corroborates prior PUL findings and allows for a more detailed characterization of the perioperative and early postoperative subject experience with the prostatic urethral lift procedure. The procedure can be tolerated under local anesthesia, requires only modest use of postoperative catheterization, and offers significant LUTS relief within 2 weeks on average with mitigation of the associated mild to moderate adverse effects within the first month.

Perioperative experience

The PUL is well tolerated under local anesthesia, typically with oral sedation and analgesia. No procedure was abandoned due to subject discomfort or device issue, and no subject required general anesthesia conversion for pain. The screening flexible cystoscopy

TABLE 4. **Treatment related adverse events**

	All			De novo (not pre-existing)		
	Events	Subjects		Events	Subjects	
	n	n	%	n	n	%
Serious adverse events	0	0	0%	0	0	0%
Non-serious adverse events	120	47	92%	89	45	88%
Hematuria	40	40	78%	38	38	75%
Dysuria	40	37	73%	29	27	53%
Incontinence	15	12	24%	2	2	4%
Pelvic pain/discomfort	11	10	20%	9	8	16%
Urgency	6	4	8%	6	4	8%
Retention	3	3	6%	3	3	6%
Penile pain	2	2	4%	2	2	4%
Urinary frequency	2	2	4%	0	0	0%
Urine flow decreased	1	1	2%	0	0	0%

can provide an indication of the level of discomfort a patient might experience with PUL. In this study, subjects who reported minimal pelvic pain (pain scores < 3 out of 10) during screening flexible cystoscopy were likely in 71% of the procedures to report a maximum score of 5 or less during PUL. By the end of the PUL procedure, the average pain score returned to 3.4, a level similar to that after flexible cystoscopy (3.0). Those subjects who experienced pelvic pain VAS of 6 or greater with flexible cystoscopy experienced an average of 7.8 during the PUL procedure. In order to optimize pain control, pelvic pain score during flexible cystoscopy could be used as a baseline screening metric to adjust pre-treatment sedation strategy.

Postoperative catheterization for this study was less than that reported in prior studies. Eighty percent of patients voided successfully after PUL, and the average catheterization time for all patients was 16 hours. As the investigators in this study had each participated in prior studies,[8,9] the improved rate of catheter-free treatment is likely due to a learning curve effect. Overall treatment time was 10 to 15 minutes shorter than prior studies (52 minutes on average), again likely reflective of technique refinement requiring less time to determine the optimal location for each implant. The overall number of implants required (3.7 per prostate) was approximately one implant less than prior studies, likely reflecting the prostate size which was on average 4 cc to 10 cc less than prior reported cohorts. All subjects underwent day surgery and returned home the day of treatment. This stands in contrast to TURP and laser therapies that recent studies show typically require 2 days of catheterization and often require 1-3 days of hospitalization.[5,24]

Early postoperative experience

The recovery experience after PUL was assessed with multiple validated instruments; this characterization of the first postoperative month has not previously been studied or presented. The average reported return to preoperative activity was 5 days, and 86% of subjects reported high quality recovery by 1 month, as measured by the validated QoR VAS scale. Ninety percent of subjects reported improvement in their symptoms in 1 month. Postoperative work productivity was characterized in the 60% of study subjects who were employed. Validated instruments indicate that most (73%) of PUL subjects lost no time from work by 2 weeks and subjects reported only 3% mean overall work impairment by 1 month.

Adverse events experienced by subjects in the trial were Clavien-Dindo classification grade I and typically transient in nature. Patients should be advised of the likelihood of transient, mild to moderate hematuria, dysuria, urgency and pelvic discomfort. No subjects were found to have bladder neck stricture, in contrast to 2% for TURP during the same period in other studies.[5] Similarly, no subject experienced bleeding leading to intervention, in contrast to 1%-4% for laser and TURP during the same period.[5]

No subject reported stress incontinence, and only two subjects (4%) reported de novo non-stress incontinence. In contrast, a recent randomized study shows that TURP and laser vaporization are associated with 3%-11% de novo incontinence.[5] A significant number of those events has been found to be of the more debilitating stress incontinence type.[5] Some reports indicate that the actual number of subjects experiencing incontinence to some degree at time of discharge after TURP may be as much as 80%, with 42% of subjects incontinent for more than 4 weeks.[25]

No subject experienced any sexual dysfunction adverse event. In sexually active men, erectile function as measured by the SHIM did not significantly change from the average baseline value. Ejaculatory function as measured by the MSHQ-EjD did improve significantly in both the function and bother domains, consistent with prior PUL results. PUL is perhaps most highly differentiated from other BPH procedures in that it has been shown to preserve both erectile and ejaculatory function.

The therapeutic effect of PUL in this study is similar to prior reported values of comparable subjects in other studies. The 5.7 point improvement in IPSS at 2 weeks is consistent with the 4.1 point improvement found in the L.I.F.T. pivotal study and the 4.5 point improvement presented in the cross-over study at the same time point.[8,9] At 1 month, the response to treatment progressed to an average 10.5 point improvement, similar to the 9.8 point change seen in the L.I.F.T. study and the 10.9 point change found in the cross-over study.[8,9] These symptom improvements are comparable to surgical intervention and far superior to reported improvements using medical therapy.[2] Further, improvements in urinary flow, QoL and BPHII track consistently with IPSS and previously published results.[8,9] By definition, the BPHII change seen in this study is considered to be a "marked improvement," which is the greatest that can be expected.[26] This level of LUTS improvement with the rapid recovery, coupled with preservation of sexual function prompted 75% of subjects to state they would recommend PUL to a friend suffering from BPH related LUTS.

A limitation of this study is the short follow up period; overall therapeutic durability will be assessed in other trials and publications. For this study, most

subjects returned to their preoperative activity level and reported surgical recovery within this follow up period, thus allowing for sufficient characterization of the recovery experience. This study was un-blinded and single-arm. A follow on study that randomizes between PUL and another therapy would add higher quality characterization and context for LUTS treatment options.

Conclusions

PUL is tolerated under local anesthesia, can allow patients to quickly return to preoperative activity and work, and offers a recovery experience that inspires patients at 1 month to recommend the procedure to their friends. When advising a patient on what to expect with PUL, one can indicate: 1) the patient may experience discomfort during the procedure, but it has been well tolerated in general, 2) full recovery is typically achieved within 1 month with return to preoperative activity within days, 3) 90% of patients report improvement by 1 month, and 4) sexual function is typically preserved.

The PUL procedure can provide rapid symptom relief, significant urinary flow rate increase, significant improvements in quality of life parameters, and preserve sexual function for men suffering from symptomatic LUTS secondary to BPH in an outpatient, minimally invasive procedure performed comfortably under local anesthetic.

Disclosure

Drs. Shore, Freedman, Gange, Moseley, Heron, Tutrone and Brown were investigators in this study. Dr. Gange is a NxThera investigator, Lilly speaker, and Auxilium speaker. Dr. Barkin was a principal investigator for the original UroLift trial and has performed a number of commercial installations in Canada. □

References

1. Haltbakk J, Hanestad BR, Hunskaar S. How important are men's lower urinary tract symptoms (LUTS) and their impact on the quality of life (QOL)? *Qual Life Res* 2005;14(7):1733-1741.
2. Roehrborn CG, McConnell JD, Barry MJ et al. American Urological Association Guideline: Management of benign prostatic hyperplasia (BPH). American Urological Association Education and Research Inc. 2010.
3. Verhamme KM, Dieleman JP, Bieumink GS et al. Treatment strategies, patterns of drug use and treatment discontinuation in men with LUTS suggestive of benign prostatic hyperplasia: The Triumph Project. *Eur Urol* 2003;44(5):539.
4. Miano R, De Nunzio C, Asimakopoulos AD, Germani S, Tubaro A. Treatment options for benign prostatic hyperplasia in older men. *Med Sci Monit* 2008:14(7):RA94-102.
5. Bachmann A, Tubaro A, Barber N et al. 108-W XPS GreenLight laser vaporization versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-Month safety and efficacy results of a European multicenter randomized trial-the GOLIATH study. *Eur Urol* 2013 Nov 11. Epub ahead of print.
6. Woo HH, Chin PT, McNicholas TA et al. Safety and feasibility of the Prostatic Urethral Lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). *BJU Int* 2011;108(1):82-88.
7. Chin PT, Boiton DM, Jack G et al. Prostatic Urethral Lift: two-year results after treatment for lower urinary symptoms secondary to benign prostatic hyperplasia. *Urology* 2012;79(1): 5-11.
8. Roehrborn CG, Gange SN, Shore ND et al. Multi-center randomized controlled blinded study of the Prostatic Urethral Lift for the treatment of LUTS associated with prostate enlargement due to BPH: the LIFT study. *J Urol* 2013;190(6):2161-2167.
9. Cantwell AL, Bogache WK, Richardson SF et al. Multi-center prospective crossover study of the Prostatic Urethral Lift for the treatment of LUTS secondary to BPH. *BJU Int* In Press.
10. McVary KT, Gange SN, Shore ND et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. *J Sex Med* 2013 Sep 30. Epub ahead of print.
11. Woo HH, Bolton DM, Laborde E et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Sex Med* 2012;9(2):568-575.
12. U.S. Food and Drug Administration, Center for Devices and Radiological Health, K130651 NeoTract UroLift System, Model REF UL400 approval letter, September 13, 2013. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368325.htm
13. Barkin J, Giddens J, Incze P et al. UroLift system for relief of prostate obstruction under local anesthesia. *Can J Urol* 2012;19(2): 6217-6222.
14. Myles PS, Hunt JO, Nightingale CE et al. Development and psychometric testing of a quality of recovery score after general anesthesia and surgery in adults. *Anesth Analg* 1999;88(1):83-90.
15. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. *Am J Obstet Gynecol* 2003;189(1): 98-101.
16. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993;4(5):353-365.
17. Barry MJ, Fowler FJ Jr, O'Leary MP et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J Urol* 1992;148(5):1549-1557.
18. Barry MJ, Fowler FJ Jr, O'Leary MP et al. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of the American Urology Association. *Med Care* 1995;33(4 Suppl):AS145-155.
19. Rosen RC, Riley A, Wagner G et al. The international index of erectile function (IIEF): A multidimensional scale for assessment of erectile dysfunction. *Urology* 1997;49(6):822-830.
20. Rosen RC, Cappelleri JC, Smith MD et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. *Int J Impot Res* 1999;11(6):319-326.

21. Rosen RC, Catania JA, Althof SE et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. *Urology* 2007;69(5):805-809.
22. Grino P, Bruskewitz R, Blaivis J et al. Maximum urinary flow rate by uroflowmetry: automatic or visual interpretation. *J Urol* 1993;149(2):339-341.
23. Mamoulakis C, Efthimiou I, Kazoulis S et al. The modified Clavien classification system: a standardized platform for reporting complications in transurethral resection of the prostate. *World J Urol* 2011;29:205-210.
24. Goh AC and Gonzalez RR. Photoselective laser vaporization prostatectomy versus transurethral prostate resection: a cost analysis. *J Urol* 2010;183:1469-1473.
25. Mogensen K, Jacobsen JD. The load on family and primary healthcare in the first six weeks after transurethral resection of the prostate. *Scand J Urol Nephrol* 2008;42(2):132-136.
26. Barry MJ, Williford WO, Chang Y et al. Benign prostatic hyperplasia specific health status measures in clinical research: How much change in the American Urological Association Symptom Index and the Benign Prostatic Hyperplasia Impact Index is perceptible to patients? *J Urol* 1995;154:1770-1774.